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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Donald W. Landry and Juan A. Oliver	**Examiner:**	Not yet known
Serial No.:	10/789,548	**Group Art Unit:**	Not yet known
Filed:	February 26, 2004	**Docket No.:**	30000.2USU1
Title:	A METHOD FOR STABILIZING BLOOD PRESSURE IN HEMODIALYSIS SUBJECTS		

CERTIFICATE UNDER 37 CFR §1.8:
I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on August 11, 2004.

By: Renato Marco P. Domingo

INFORMATION DISCLOSURE STATEMENT (37 C.F.R. § 1.97(b)(3))

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

With regard to the above-identified application, the items of information listed on the enclosed Form 1449 are brought to the attention of the Examiner. They are as follows:

- International Publication No. WO84/03564 published September 13, 1984 – **Exhibit 1**
- Aisenbrey, Gary A. et al., "Vascular Effects of Arginine Vasopressin during Fluid Deprivation in the Rat," *The Journal of Clinical Investigation*, 1981, 67:961-8 – **Exhibit 2**
- Ardaillou, Raymond et al., "Secretion and Catabolism of Antidiuretic Hormone in Renal Failure," *Contributions to Nephrology*, 1986, 50:46-53 – **Exhibit 3**
- Argent, Nicholas B. et al., "Metabolic clearance rate of arginine vasopressin in severe chronic renal failure," *Clinical Science*, 1992, 83:583-7 – **Exhibit 4**
- Baldamus, C. A. et al., "Sympathetic and Hemodynamic Response to Volume Removal during Different Forms of Renal Replacement Therapy," *Nephron*, 1982, 31:324-32 – **Exhibit 5**

- Benmansour, Mustapha et al., "Metabolic clearance rate of immunoreactive vasopressin in man," *European Journal of Clinical Investigation*, 1982, 12:475-80 – **Exhibit 6**
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- Charra, Bernard et al., "Control of Hypertension and Prolonged Survival on Maintenance Hemodialysis," *Nephron*, 1983, 33:96-9 – **Exhibit 10**
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- Daul, Anton E. et al., "Arterial hypotension in chronic hemodialyzed patients," *Kidney International,* 1987, 32:728-35 – **Exhibit 13**
- Dunn, Fredrick L. et al., "The Role of Blood Osmolality and Volume in Regulating Vasopressin Secretion in the Rat," *The Journal of Clinical Investigation,* 1973, 52:3212-9 – **Exhibit 14**
- Endou, Kyoko et al., "Hemodynamic Changes during Hemodialysis," *Cardiology*, 1978, 63:175-87 – **Exhibit 15**
- Ewing, D. J. and R. Winney, "Autonomic Function in Patients with Chronic Renal Failure on Intermittent Haemodialysis," *Nephron*, 1975, 15:424-9 – **Exhibit 16**

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- Friess, U. et al., "Failure of arginine-vasopressin and other pressor hormones to increase in severe recurrent dialysis hypotension," *Nephrology Dialysis Transplantation*, 1995, 10:1421-7 – **Exhibit 19**
- Graybiel, Ashton and R. Earle Glendy, "Circulatory Effects Following the Intravenous Administration of Pitressin in Normal Persons and in Patients with Hypertension and Angina Pectoris," *The American Heart Journal*, 1941, 21:481-9 – **Exhibit 20**
- Grollman, Arthur and E. M. K. Geiling, "The Cardiovascular and Metabolic Reactions of Man to the Intramuscular Injection of Posterior Pituitary Liquid (Pituitrin), Pitressin and Pitocin," *The Journal of Pharmacology & Experimental Therapeutics*, 1932, 46:447-60 – **Exhibit 21**
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- Kaliszan, R. et al., "Constrictory Activity of Three New Arginine-Vasopressin (AVP) Analogues (ALA-AVP, SER-ALA-AVP, THR-SER-ALA-AVP) Towards Isolated Rat Tail Artery as Related to AVP Alone," *Pharmacological Research Commununications*, 1988, 20:377-81 – **Exhibit 33**
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- Landry, Donald W. and Juan A. Oliver, "The Pathogenesis of Vasodilatory Shock," *The New England Journal of Medicine*, 2001, 345:588-95 – **Exhibit 37**

- Lazarus, J. Michael et al., "Hemodialysis," *The Kidney*, 1996, 5th ed., W.B. Saunders Co., Chapter 56, pp 2424-2506 – **Exhibit 38**
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- Nakashima, Yoshiyuki et al., "Localization of Autonomic Nervous System Dysfunction in Dialysis Patients," *American Journal of Nephrology*, 1987, 7:375-81 – **Exhibit 44**
- Nakayama, Masaaki et al., "Stimulated Secretion of Arginine Vasopressin during Hemodialysis in Patients with Hemodialysis Hypotension," *Nephron*, 1998, 79:488-9 – **Exhibit 45**
- Nies, Alan S. et al., "Hemodialysis hypotension is not the result of uremic peripheral autonomic neuropathy," *The Journal of Laboratory and Clinical Medicine*, 1979, 94:395-402 – **Exhibit 46**
- Padfield, P. L., "Changes of Vasopressin in Hypertension: Cause Or Effect?" *The Lancet*, 1976, 1:1255-7 – **Exhibit 47**
- Pierratos, Andreas et al., "Nocturnal Hemodialysis: Three-Year Experience," *Journal of the American Society of Nephrology*, 1998, 9:859-68 – **Exhibit 48**

- Price, M. R. et al., "Epitope analysis of monoclonal antibody NCRC-11 defined antigen isolated from human ovarian and breast carcinomas," *British Journal of Cancer*, 1986, 54:393-400 – **Exhibit 49**
- Rosansky, S. J. et al., "Effect of osmolar changes on plasma arginine vasopressin (PAVP) in dialysis patients," *Clinical Nephrology*, 1991, 35:158-64 – **Exhibit 50**
- Rouby, Jean J. et al., "Hemodynamic changes induced by regular hemodialysis and sequential ultrafiltration hemodialysis: A comparative study," *Kidney International*, 17:801-10 – **Exhibit 51**
- Santoro, A. et al., "A Haemodynamic Study of Hypotension During Haemodialysis Using Electrical Bioimpedance Cardiography," *Nephrology Dialysis Transplantation*, 1990, 5(Suppl 1):147-53 – **Exhibit 52**
- Schwartz, Jeffrey and Ian A. Reid, "Effect of Vasopressin Blockade on Blood Pressure Regulation During Hemorrhage in Conscious Dogs," *Endocrinology*, 1981, 109:1778-80 – **Exhibit 53**
- Schwartz, Jeffrey et al., "Role of Vasopressin in Blood Pressure Regulation during Adrenal Insufficiency," *Endocrinology*, 1983, 112:234-8 – **Exhibit 54**
- Shade, R. E. and L. Share, "Metabolic Clearance of Immunoreactive Vasopressin and Immunoreactive [^{131}I]iodo Vasopressin in the Hypophysectomized Dog," *Endocrinology*, 1976, 99:1199-1206 – **Exhibit 55**
- Shaldon, S., "Progress from Haemodialysis," *Nephron,* 1981, 27:2-6 – **Exhibit 56**
- Shimamoto, Kazuaki et al., "A Study of Plasma Vasopressin in Patients Undergoing Chronic Hemodialysis," *Journal of Clinical Endocrinology & Metabolism*, 1977, 45:714-20 – **Exhibit 57**
- Shimamoto, Kazuaki et al., "Permeability of Antidiuretic Hormone and Other Hormones Through the Dialysis Membrane in Patients Undergoing Chronic Hemodialysis," *Journal of Clinical Endocrinology & Metabolism*, 1977, 45:818-20 – **Exhibit 58**
- Shiota, Jun et al., "Plasma Atrial Natriuretic Peptide during Hemodialysis with or without Fluid Removal," *Nephron*, 1990, 55:283-6 – **Exhibit 59**

- Sjöquist, P. O. B. et al., "Effect of a Vasopressin Analogue (N^{α}-glycyl-glycyl-glycyl-[8-lysine]-vasopressin) on Organ Blood Flow in the Pregnant Guinea Pig," *Acta Pharmacologica et Toxicologica*, 1977, 40:369-77 – **Exhibit 60**
- Sjöquist, P. O. B. et al., "Actions of a New Vasopressin Analogue (1-deamino-6-carba-[8-arginine]-vasopressin) on Regional Blood Flow in Pregnant Guinea Pigs," *Acta Pharmacologica et Toxicologica*, 1978, 43:190-5 – **Exhibit 61**
- Smith, Clark W. and Martha F. Ferger, "Synthesis and Some Pharmacological Properties of [3-β-(2-Thienyl)-L-alanine]-8-lysine-vasopressin," *Journal of Medicinal Chemistry*, 1975, 18:822-5 – **Exhibit 62**
- Spiegel, D. M. et al., "Bioimpedance resistance ratios for the evaluation of dry weight in hemodialysis," *Clinical Nephrology*, 2000, 53:108-14 – **Exhibit 63**
- Stone, William J. and Raymond M. Hakim, "Therapeutic Options in the Management of End-stage Renal Disease," *The Principles And Practice of Nephrology*, 1995, Chap. 95, pp 650-4 – **Exhibit 64**
- Uusimaa, P. et al., "Neurohumoral responses to a single haemodialysis in chronic renal patients," *Acta Physiologica Scandinavica*, 1999, 165:25-31 – **Exhibit 65**
- Vertes, Victor et al., "Hypertension in End-Stage Renal Disease," *The New England Journal of Medicine*, 1969, 280:978-81 – **Exhibit 66**
- Wagner, Jr., Henry N. and Eugene Braunwald, "The Pressor Effect of the Antidiuretic Principle of the Posterior Pituitary in Orthostatic Hypotension," *The Journal of Clinical Investigation*, 1956, 35:1412-8 – **Exhibit 67**
- Weitzman, Richard E. et al., "Effect of osmolality on arginine vasopressin and renin release after hemorrhage," *American Journal of Physiology*, 1980, 238:E62-8 – **Exhibit 68**
- Zerbe, Robert L. et al., "Vasopressin Response to Orthostatic Hypotension," *The American Journal of Medicine*, 1983, 74:265-71 – **Exhibit 69**
- Ziegler, Michael G. et al., "Norepinephrine clearance, chromogranin A and dopamine β hydroxylase in renal failure," *Kidney International*, 1990, 37:1357-62 – **Exhibit 70**

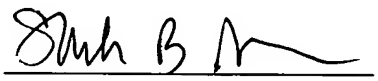
This statement should be considered because it is submitted before the mailing date of the first Office Action on the merits according to 37 C.F.R. §1.97(b)(3). In accordance with 37 C.F.R. §1.98(a)(2), copies of each document or other information listed on the enclosed Form 1449 are provided.

No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102 and 103 and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish that the reference(s) are not "prior art." Moreover, Applicants do not represent that the references have been thoroughly reviewed or that any relevance of any portion of a reference is intended.

Consideration of the items listed is respectfully requested. Pursuant to the provisions of M.P.E.P. § 609, it is requested that the Examiner return a copy of the attached Form 1449, marked as being considered and initialed by the Examiner, to the undersigned with the next official communication.

No fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee, or credit any overpayment, to Deposit Account No. 50-0306.

Respectfully submitted,



Sarah B. Adriano
Registration No. 34,470
SaraLynn Mandel
Registration No. 31,853
Mandel & Adriano
55 S. Lake Avenue, Suite 710
Pasadena, California 91101
(626) 395-7801
Customer No. 26,941

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Donald W. Landry and Juan A. Oliver
Serial No.:	10/789,548
Filed:	February 26, 2004
Docket:	30000.2USU1
Title:	A METHOD FOR STABILIZING BLOOD PRESSURE IN HEMODIALYSIS SUBJECTS

CERTIFICATE UNDER 37 CFR §1.8
I hereby certify that this paper or fee is being deposited with the United States Postal as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on August 11, 2004.

By: Renato Marco P. Domingo
Name: Renato Marco P. Domingo

55 S. Lake Avenue, Suite 710
Pasadena, California 91101
August 11, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

We are transmitting herewith the attached:

- ☒ Transmittal sheet, in duplicate, containing Certificate under 37 CFR §1.8
- ☒ Information Disclosure Statement (37 C.F.R. §1.97(b)(3)) (8 pages)
- ☒ Form 1449 (Information Disclosure Statement) (5 sheets)
- ☒ Exhibits 1-70 (References)
- ☒ Return postcard

Please charge any additional fees or credit overpayment to Deposit Account No. 50-0306. A duplicate of this sheet is enclosed.

MANDEL & ADRIANO
55 S. Lake Avenue, Suite 710
Pasadena, California 91101
(626) 395-7801

By: Sarah B Ad
Name: Sarah B. Adriano
Reg. No.: 34,470
Customer No. 26,941

FORM 1449*	Docket Number	Application Number
INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION	30000.2USU1	10/789,548
	Applicants	
	Donald W. Landry and Juan A. Oliver	
(Use several sheets if necessary)	Filing Date	Group Art Unit
	February 26, 2004	Not yet known

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS							
	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	WO84/03564 **(Exhibit 1)**	09/13/84	PCT				X

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
		Aisenbrey, Gary A. et al., "Vascular Effects of Arginine Vasopressin during Fluid Deprivation in the Rat," *The Journal of Clinical Investigation,* 1981, 67:961-8 **(Exhibit 2)**
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.

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	Donald W. Landry and Juan A. Oliver	
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		Nakashima, Yoshiyuki et al., "Localization of Autonomic Nervous System Dysfunction in Dialysis Patients," *American Journal of Nephrology,* 1987, 7:375-81 **(Exhibit 44)**
		Nakayama, Masaaki et al., "Stimulated Secretion of Arginine Vasopressin during Hemodialysis in Patients with Hemodialysis Hypotension," *Nephron,* 1998, 79:488-9 **(Exhibit 45)**
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		Padfield, P. L., "Changes of Vasopressin in Hypertension: Cause Or Effect?" *The Lancet,* 1976, 1:1255-7 **(Exhibit 47)**
		Pierratos, Andreas et al., "Nocturnal Hemodialysis: Three-Year Experience," *Journal of the American Society of Nephrology,* 1998, 9:859-68 **(Exhibit 48)**
		Price, M. R. et al., "Epitope analysis of monoclonal antibody NCRC-11 defined antigen isolated from human ovarian and breast carcinomas," *British Journal of Cancer,* 1986, 54:393-400 **(Exhibit 49)**
		Rosansky, S. J. et al., "Effect of osmolar changes on plasma arginine vasopressin (PAVP) in dialysis patients," *Clinical Nephrology,* 1991, 35:158-64 **(Exhibit 50)**
		Rouby, Jean J. et al., "Hemodynamic changes induced by regular hemodialysis and sequential ultrafiltration hemodialysis: A comparative study," *Kidney International,* 17:801-10 **(Exhibit 51)**

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INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION	30000.2USU1	10/789,548
	Applicants: Donald W. Landry and Juan A. Oliver	
(Use several sheets if necessary)	Filing Date: February 26, 2004	Group Art Unit: Not yet known

		OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
		Santoro, A. et al., "A Haemodynamic Study of Hypotension During Haemodialysis Using Electrical Bioimpedance Cardiography," *Nephrology Dialysis Transplantation,* 1990, 5(Suppl 1):147-53 **(Exhibit 52)**
		Schwartz, Jeffrey and Ian A. Reid, "Effect of Vasopressin Blockade on Blood Pressure Regulation During Hemorrhage in Conscious Dogs," *Endocrinology,* 1981, 109:1778-80 **(Exhibit 53)**
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		Shade, R. E. and L. Share, "Metabolic Clearance of Immunoreactive Vasopressin and Immunoreactive [^{131}I]iodo Vasopressin in the Hypophysectomized Dog," *Endocrinology,* 1976, 99:1199-1206 **(Exhibit 55)**
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		Shimamoto, Kazuaki et al., "A Study of Plasma Vasopressin in Patients Undergoing Chronic Hemodialysis," *Journal of Clinical Endocrinology & Metabolism,* 1977, 45:714-20 **(Exhibit 57)**
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		Spiegel, D. M. et al., "Bioimpedance resistance ratios for the evaluation of dry weight in hemodialysis," *Clinical Nephrology,* 2000, 53:108-14 **(Exhibit 63)**
		Stone, William J. and Raymond M. Hakim, "Therapeutic Options in the Management of End-stage Renal Disease," *The Principles And Practice of Nephrology,* 1995, Chap. 95, pp 650-4 **(Exhibit 64)**
		Uusimaa, P. et al., "Neurohumoral responses to a single haemodialysis in chronic renal patients," *Acta Physiologica Scandinavica,* 1999, 165:25-31 **(Exhibit 65)**
		Vertes, Victor et al., "Hypertension in End-Stage Renal Disease," *The New England Journal of Medicine,* 1969, 280:978-81 **(Exhibit 66)**
		Wagner, Jr., Henry N. and Eugene Braunwald, "The Pressor Effect of the Antidiuretic Principle of the Posterior Pituitary in Orthostatic Hypotension," *The Journal of Clinical Investigation,* 1956, 35:1412-8 **(Exhibit 67)**
		Weitzman, Richard E. et al., "Effect of osmolality on arginine vasopressin and renin release after hemorrhage," *American Journal of Physiology,* 1980, 238:E62-8 **(Exhibit 68)**

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		Zerbe, Robert L. et al., "Vasopressin Response to Orthostatic Hypotension," *The American Journal of Medicine,* 1983, 74:265-71 **(Exhibit 69)**
		Ziegler, Michael G. et al., "Norepinephrine clearance, chromogranin A and dopamine β hydroxylase in renal failure," *Kidney International,* 1990, 37:1357-62 **(Exhibit 70)**

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